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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
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In re Application of :
BORDON-PALLIER et al :
Serial No.: 09/831,426 : Decision on Petition
Filing Date: 8 May 2001 :
Attorney Docket No. 146.1364 :

This letter is in response to the Petition filed under 37 CFR 1.181, to review the restriction requirement, filed with a certificate of mailing date of 28 August 2003. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed under 35 USC 371 on 8 May 2001. Original claims 1-16 were directed to nucleic acid molecules, host cells, polypeptides, method of preparing the polypeptide, plasmids, expression vectors and methods of using the polypeptide or nucleic acid for treatment. A preliminary amendment filed with the application corrected the claim dependency for claims 3-12, canceled claims 15-16 and added new claims 17-18.

In Paper No. 17, mailed 26 February 2003, the Office restricted the claims into seven groups as summarized below:

Group I, Claims 1, 2, 3, 12, 13, 15, 16 drawn to a DNA sequence of hTFIIIA gene encoding for the amino acid sequence of SEQ ID NO 2, containing SEQ ID No 3, an expression vector, host cell and method of using for diagnosis or treatment.

Group II, Claims 1, 2, 4, 12, 13, 15, 16 drawn to a DNA sequence of hTFIIIA gene encoding for the amino acid sequence of SEQ ID NO 2, containing SEQ ID No 4, an expression vector, host cell and method of using for diagnosis or treatment.

Group III, Claims 1, 5, 12, 13, 15, 16 drawn to a DNA sequence of hTFIIIA gene having a sequence beginning at nucelocite 176 and finishing at 1270 of SEQ ID No 3, an expression vector, host cell and method of using for diagnosis or treatment.

Group IV, Claims 1, 6, 12, 13, 15, 16 drawn to a DNA sequence of hTFIIIA gene and a DNA sequence that hybridizes to it, has homology with it or fragments of it, an expression vector, host cell and method of using for diagnosis or treatment.

Group V, Claims 1, 7, 8, 9, 12, 13, 15, 16 drawn to a DNA sequence of hTFIIIA gene comprising modification introduced by suppression, insertion and/or substitution, an expression vector, host cell and method of using for diagnosis or treatment.

Group VI, claims 10, 11, 15 and 16, drawn to a polypeptide having the function of hTFIIIIA, a method of making and a method of using the protein for diagnosis or treatment.

Group VII, claims 14, drawn to a plasmid deposited under CNCM no. 1-2701.

The Office reasoned that Inventions I-V are all structurally, functionally and chemically unrelated. Further more the protein, method of making the protein and method of using are for different and unrelated purposes. No reasons were provided for Group VII. It is noted that the restriction did not take into account the cancellation of claims 15-16 and addition of claims 17-18, by preliminary amendment.

In Paper No. 18, filed 25 March 2003, Applicant elected Group I, with traverse.

In Paper No. 19, mailed 4 June 2002, the examiner considered the arguments but deemed them not to be persuasive as follows:

> The different inventions refer to different sequences that correspond to different sequences that encode different proteins. Because the nucleotide sequences encode different proteins, they cannot possibly be the same protein otherwise the protein claimed would be have the same sequence identification numbers.

The restriction requirement was made final.

Claims 4-11 and 14 were withdrawn from consideration as being drawn to a non-elected invention and claims 15-16 were canceled by amendment.

Claims 1-3, 12-13 and 17-18 were examined on the merits. Claims 1-3 and 13 were rejected under 35 USC 101 as being directed to non-statutory subject matter. Claims 1-3, 12-13 and 17-18 were rejected under 35 USC 101 because the invention is not supported by a specific or well established utility. Claims 17 and 18 were rejected under 35 USC 112, first paragraph, for lack of enablement. Claims 1, 17 and 18 were rejected under 35 USC 102(b) as being anticipated by Fujiwara et al. Claim 1 was rejected under 35 USC 102(b) as being anticipated by Seifart et al. Claim 1 was rejected under 35 USC 102(b)

as being anticipated by Moorefield et al. Claims 1-3 were rejected under 35 USC 102(b) as being anticipated by Arakawa et al.

Claims 1-3 and 12-13 were rejected under 35 USC 102(f) because applicant did not invent the claimed subject matter.

This petition was then filed, concurrent with an amendment to cancel claim 1, and amend claims 2-12 and 17. It is noted that amended claim 2 improperly depends upon canceled claim 1. This informality may be corrected by a supplemental amendment or by an examiners amendment at time of allowance.

DISCUSSION

The application, file history and petition have been considered carefully.

The petition correctly states that the application filed under 35 USC 371 is subject to unity of invention standard and not US Restriction Requirement as for applications filed under 35 USC 111(a). The Petition then points to PCT Rule and MPEP sections 1850 and 1893.03(d), which govern unity of invention standard. Although the restriction requirement cited 35 USC 372, PCT Rule 13.1 and 37 CFR 1.499, the petition correctly points out that the groupings and reasoning failed to apply the PCT standards.

Claims 1-7, as pending at time of restriction requirement, are set forth below.

> 1. DNA sequence of the hTFIIIA gene coding for a protein having biological function of human transcription factor TFIIIA.
>
> 2. DNA sequence of hTFIIIA gene of the human transcription factor hTFIIIA according to claim 1, coding for the amino acid sequence SEQ ID No. 2.
>
> 3. DNA sequence of hTFIIIA gene according to claim 1, containing the nucleotide sequence SEQ ID No. 3.
>
> 4. DNA sequence of hTFIIIA gene according to claim 1, containing the nucleotide sequence SEQ ID No. 4.
>
> 5. DNA sequence according to claim 4, having the sequence beginning at nucleotide 176 and finishing at the nucleotide 1270 of SEQ ID No. 3.
>
> 6. DNA sequence coding for the human transcription factor hTFIIIA according to claim 1, as well as the DNA sequence which hybridize with it and/or show a significant homology with this sequence or fragments of it and which code for a protein with the same function.

7. DNA sequence according to claim 1, comprising modification introduced by suppression, insertion and/or substitution of at least one nucleotide coding for a protein with the same biological activity as human transcription factor hTFIIIA

The restriction requirement placed claims 3, 4, 5, 6, and 7, which all depend upon claim 1, each into separate Group I-V, respectively. Claim 1 was placed in Groups I-V. Claim 2 was placed in Groups I and II.

The petition asserts that the dependent claims 3, 4, 5, 6 and 7 further limit the independent claim1 and should not be considered as separate inventions from that in the independent claim. The dependent claims appear to be grouped as presenting alternatives when in fact, they present claims encompassing the same subject matter, with differences in scope. If alternative groups of molecules had been claimed, the Examiner should have followed the guidance in PCT Administrative Instructions, Annex B, Markush Practice. This was not done. The Petition further explains that all claims 2-9, 12 and 14 encompass sequences that encode for SEQ ID No. 2. Because these arguments are persuasive and because the same product cannot be placed in more than one group for examination purposes, Groups I-V and VII are rejoined.

Since the examiner failed to demonstrate in the lack of unity determination that the technical feature of Group I did not make a contribution over the prior art, the first method of use, expressing the DNA to make protein (Claim 11) should be grouped with the first product (Claim 1). A further review of the restriction requirement shows that the examiner placed Claim 11 in Group VI, along with claim 10, the polypeptide and claims 15 and 16 (presumably intending pending claims 17 and 18) drawn to the first method of using the polypeptide. Accordingly, Group VI will be rejoined with Group I.

DECISION

The petition is **GRANTED** for the reasons set forth above.

The application is being returned to the examiner for consideration of the amendment and response filed 8 September 2003 and for completion of an Office action on claims as pending.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA, 22313-1450 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 308-7230.

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